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10/529,131	11/07/2005	John P. Maye	61843USN(51035)	2561

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,131	MAYE, JOHN P.	
	Examiner	Art Unit	
	MICHELE FLOOD	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 16, 2010 has been entered.

Acknowledgment is made of the receipt and entry of the amendment filed herein with the cancellation of Claim 12.

Any objection or rejection set forth in the previous Office action mail dated December 12, 2009 and not repeated herein is withdrawn.

Claims 1-5 and 11 are under examination.

Response to Arguments

Claim Objections

Claim 1 is objected to because of the following informalities: There is an apparent misspelling in Claim 1, line 2. Applicant may overcome the objection by replacing "*ruminatium*" with *ruminantium*. Appropriate correction is required. Newly applied.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 11, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims are rejected for failing to provide prior support or antecedent basis for the language “aqueous alkali solution of hop acids” in Claims 1, 2 and 5; and for the language “wherein the aqueous alkali solution of hop acids comprises hop acid salts" in Claims 2 and 5. Newly applied as necessitated by amendment.

Claim 1, as set forth in the amendment filed on June 16, 2010, now recites “A method of preparing a food supplement useful to inhibit *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* or *Methanobacterium ruminatium* for livestock comprising mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids is mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* and *Methanobacterium ruminantium*, commonly found in digestive systems of livestock”.

Claim 2, as set forth in the amendment filed on June 16, 2010, now recites "The method of claim 1 wherein the aqueous alkali solution of hop acids comprises hop acid salts which are selected from at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids ad hexahydroisoalpha acids".

Claim 5, as set forth in the amendment filed on June 16, 2010, now recites "The method of claim 1 wherein the aqueous alkali solution of hop acids comprises hop acid salts which are mixed with the feed resulting in an amount of 2 parts per million (ppm) of hop acid present in fluid of the digestive systems of livestock".

However, the specification as originally filed provides only for a method of preparing a food supplement useful to inhibit claim-designated microorganisms for livestock comprising mixing hop acids with a livestock feed.

Insertion of the mentioned claim limitations has no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of a method of preparing a food supplement useful to inhibit *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* or *Methanobacterium ruminantium* for livestock comprising mixing an aqueous alkali solution of hop acids or salts thereof for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids and/or salts thereof are mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococus albus, R. flavefaciens, Butyrivibrio*

fibrisolvens, and *Methanobacterium ruminantium*, commonly found in digestive systems of livestock. There are only two exemplified methods for preparing the claim-designated livestock feed comprising mixing beta acids with barley as set forth in Example 4 for controlling the growth of gram-positive bacteria *Ruminococcus albus, R. flavefaciens and Butyrivibrio fibrisolvens*; and, on page 5 of the specification comprising mixing alpha acids or beta acids with alfalfa, as set forth in Example 7, on pages 7 and 8 for reducing or controlling methane-producing bacteria, such as the claim-designated *Methanobacterium ruminantium.* This is not sufficient support for the new genus: "aqueous alkali solution of hop acids" and/or "wherein the aqueous alkali solution of hop acids comprises hop acid salts". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations is considered to be the insertion of new matter for the above reasons. As the above-mentioned claim limitations could not be found in the present specification, the recitation of the claim limitations is deemed new matter.

In the REMARKS" (last paragraph of page 3 to page 5) filed on June 16, 2010, Applicant argues:

"Applicants submit that the hop acids used in the Examples of the Applicants' specification can be found at Example 10, which lists a number of commercially available hop acid products. Such products include Isohop ™, Betastab ™, Alphahop ™, Tetrahop ™,

Hexahop ™, HHBA ™, and Redihop ™. Applicants submit that one of ordinary skill in the art is aware that such hop acid products include the hop acids as an aqueous alkali solution.

Applicants contend that prior to the filing and/or priority date of the instant application, those of ordinary skill in the art were aware that Isohop ™, Betastab ™, Alphahop ™, Tetrahop ™, Hexahop ™, HHBA ™, and Redihop ™ were aqueous alkaline solutions of hop acids. Attached as Exhibit A are the certificates of analyses for the above hop products, which were provided to the purchasers of the above hop products as early as 1999 or 2000. Each certificate of analysis states that each of the above hop products comprises an aqueous alkaline solution of a salt of a hop acid. Such disclosures to purchasers indicate that those of ordinary skill in the art (the purchasers) were aware that the hop products were aqueous alkaline solutions of hop acids.

Also attached as Exhibit A are copies of brochures for Isohop, Redihop, and Tetrahop produced by a company called Cultor Food Science Brewing Ingredients. The brochures describe the hop products as being "aqueous alkaline solutions". Applicants contend that the Cultor brochure was a publically distributed document.

Further, the product data information for the above-mentioned products is either publicly available or known to those of ordinary skill in the art. For example, the product specifications of Isohop ™, Tetrahop ™, Hexahop ™, and Redihop ™ can be found at the following website: http://www.barthhaasgroup.com/index.php?option=com content&task=view&id=24&Itemid=26.

Although the documents in Exhibit A indicate that an "alkaline" solution of hop acids was provided, Applicants' claims provide for the term "alkali" for the sake of accuracy. Applicants contend that the term "alkaline" is known in the art to refer to: a) any basic (non acidic) solution; or b) salt of a 2+ metal, such as magnesium or calcium. Applicants further contend that the term "alkali" is used in the instant claims because the hop products, e.g.,

Isohop ™, Betastab ™, etc., for the sake of accuracy as the products are potassium salt (1+ metal) solutions (see Exhibit A documents).

Applicants thus contend that the specification, particularly when read in light of Examples 1-10, clearly allows one of ordinary skill in the art to recognize that Applicants were in possession of the invention directed to preparing an organic food supplement using an aqueous alkali solution of hop acids. Applicants submit that the rejection is obviated and respectfully request that the rejection be withdrawn."

Applicant's arguments have been fully considered. However, they are not persuasive. While Applicant contends that the aforementioned commercially available hops acid products listed in Example 10 on page 14 of the specification were used in the examples of Applicant's specification, other than the use of testing the efficacy of these products to inhibit the growth of *Clostridium perfringens*, there is no indication that

these particular products were used in all of the disclosed examples as an indication for being useful in the making of feed to inhibit the growth of *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* or *Methanobacterium ruminantium* in livestock such as cattle. Nowhere in the passages of Example 10 did the Office find support for the claim limitations in the as-filed specification; and, therefore they must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support. With regard to attached “Exhibit A”, the included documents only provide evidence that aqueous alkali solutions of hop acids were commercially available as early as 1999 or 2000 to "purchasers". There is no indication as to whether the purchasers purchased these products for use in the claimed invention.

Claims 1-5 and 11, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Newly applied.

This is a ‘written description’ rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, □ 1 "Written Description"

Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is *whatever is now claimed* (see page 1117).

The claims are drawn to a method of preparing a food supplement useful to inhibit *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* or *Methanobacterium ruminatium* for livestock comprising mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids is mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* and *Methanobacterium ruminantium*, commonly found in digestive systems of livestock".

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, methods of the treatment or any combination thereof. In the instant case, on page 5, under "Example 4" bridging page 6, line 9, Applicant discloses fermenting barley in an artificial gut to which 1.2 ppm, 2.5 ppm or 3.75 ppm of beta acids were added. The end

product result of the *in vitro* fermentation of barley with the beta acids indicated an increase in propionate levels. The specification states, "Thus, it appears beta acids are controlling gram-positive bacteria Ruminococcus albus, R. flavefaciens, Butyrivi[b]rio fibrisolvens". The specification does not state that the beta-acids inhibit the microorganisms. The scientific definition of inhibition is to prohibit or reduce the rate of a material or living entity. An object can be controlled without reducing or prohibiting.

Thus, Claims 1-5 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see Eli Lilly, 119 F. 3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1977).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision *(see* page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied.

The metes and bounds of Claim 5 are rendered vague and indefinite by the limitation, “wherein the aqueous alkali solution of hop acids comprises hop acid salts which are mixed with the feed resulting in an amount of 2 parts per million (ppm) of hop acid present in fluid of the digestive systems of livestock ". In the instant case, the subject matter of Claim 1 from which Claim 5 directly depends upon is drawn to a method of preparing a food supplement to inhibit clam-designated bacteria comprising mixing in an amount of an aqueous alkali solution of hop acids with a livestock feed to inhibit the claim-designated undesirable bacteria commonly found in digestive systems of livestock. However, the limitation recited in Claim 5 encompasses subject matter directed to mixing an amount of an alkali solution of hop acid with a feed to effect an amount of 2 ppm of the hop acid in the digestive system fluid of livestock upon administration of the composition prepared by the instantly claimed method. Since the amount of a drug present in the system of a treated subject upon administration thereof is predicated on factors such as the dose amount, dosage frequency, route of administration and the bioavailability of the drug when administered to the subject, as well as the concentration of the active drug contained within a pharmaceutical, describing a method of preparing a drug in terms of admixing the active ingredient with a carrier to effect delivery of a particular amount of the active ingredient to patient's

digestive fluid system is ambiguous. The lack of clarity renders the claimed subject matter to which Applicant seeks patent protection uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Millis et al. (A*). Newly applied as necessitated by amendment.

Applicant claims a method of preparing a food supplement useful to inhibit *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* or *Methanobacterium ruminatium* for livestock comprising mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids is mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococus albus, R. flavefaciens, Butyrivibrio fibrisolvens,* and *Methanobacterium ruminantium*, commonly found in digestive systems of livestock. Applicant further claims the method of claim 1 wherein the livestock is selected from the group consisting of cattle, poultry, horses, pigs and zoo animals.

Millis teaches a process comprising applying an alkaline solution containing 6 to 100 ppm beta-acids to a solid food product to incorporate 6 to 50 ppm of beta-acids in the food product to inhibit the growth of gram-positive bacteria. *See* Column 2, lines 34-

40. Millis does not specifically teach adding the beta-acid hops alkaline solution to a livestock feed. However, livestock feed is a food. Moreover, Millis teaches that the process can be applied to food products including meats. *See* Column 3, lines 26-29. Zoo animals, such as lions, eat meat. The instantly claimed method is a one-step process of for mixing an effective amount of aqueous alkali solution of hop acids for oral ingestion with a livestock feed to inhibit undesirable bacteria commonly found in the digestive systems of livestock. The amounts used in the method of Millis to prepare a food product are one and the same disclosed by Applicant as being beneficial in the making of food supplement to inhibit the claim-designated bacteria and to effect a resulting in amount of 2 ppm of hop acid present in fluid of the digestive systems of livestock. Therefore, the claimed method is inherent to the process taught by Milis.

The reference anticipates the claimed subject matter.

Claims 1-5 and 11, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Barney et al. (B*). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1 and 11 was set forth above. Applicant further claims the method of claim 1 wherein the aqueous alkali solution of hop acids comprises hop acid salts which are selected from at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids. Applicant further claims the method of claim 2 wherein the alpha acid salts are selected from at least one of the group consisting of humulone, cohumulone and adhumulone; and wherein the beta acid salts are selected from at

least one of the group consisting of lupulone, colupulone and adlupulone. Applicant further claims the method of claim 1 wherein the aqueous alkali solution of hop acids salsts are mixed with the feed resulting in an amount of 2 parts per million (ppm) of hop acid present in the fluid of the digestive system of livestock.

Barney teaches a method of preparing a food product comprising applying to a food an effective amount of an alkaline solution of beta-acid salts of hops selected from hexahydrocolupulone, tetrahydroisohumulone, and tetrahydroisohumulone to inhibit gram-positive bacteria. *See* Column 1, lines 62-66; and, Column 3, lines 60-64. Barney does not specifically teach adding the salts of beta-acid hops alkaline solution to a livestock feed. However, livestock feed is a food. Moreover, Barney teaches that the process can be applied to food products including meat or vegetables. Animal feed includes vegetables. Zoo animals, such as lions, eat meat. Moreover, the amounts used in the method of Millis to prepare a food product are one and the same disclosed by Applicant as being beneficial in the making of a food supplement to inhibit the claim-designated bacteria and to effect a resulting in amount of 2 ppm of hop acid present in fluid of the digestive systems of livestock. Therefore, the claimed method is inherent to the process taught by Barney.

The reference anticipates the claimed subject matter.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
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MCF
March 22, 2010

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